K122797



## 510(k) Summary

JAN 25 2013

**Company**
Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

**Contact**
Emily Kruetzkamp, Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc
Telephone: (513) 337-1546
Fax: (513) 337-2802
Email: ekruetzk@its.jnj.com

**Date Prepared:** September 10, 2012

**Device Name**
Trade Name: ENSEAL® G2 Articulating Tissue Sealers
Common Name: Electrosurgical Cutting and Coagulation Instruments

**Classification Names**

- Electrosurgical, Cutting & Coagulation & Accessories
  (21 CFR 878.4400, Product code GEI)
- Electrocautery, Gynecologic and Accessories
  (21 CFR 884.4120, Product code HGI)

**Predicate Device**
ENSEAL® G2 Tissue Sealers, K112033

**Device Description:**

The Ethicon Endo-Surgery ENSEAL G2 Articulating Tissue Sealers are sterile, single-use surgical instruments designed to seal and cut vessels, and to cut, grasp and dissect soft tissue during open and laparoscopic surgery.

The energy activation and knife lock are activated by a single button. The instrument shaft can be rotated using the rotation knob to facilitate visualization and enable easy access to targeted tissue. The power cord is permanently attached to the device and connects the instrument to the generator. The ENSEAL G2 Articulating Tissue Sealers include an articulation capability that allows the user to articulate the end-effector during surgical procedures.

**Indication for Use:**

The ENSEAL® G2 Articulating Tissue Sealers are indicated for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures.
The devices are bipolar electrosurgical instruments for use with the Generator GEN11 (GEN11). They are intended for use during open or laparoscopic, general and gynecological surgery to cut and seal vessels, and to cut, grasp and dissect tissue during surgery.
Indications for use include open and laparoscopic, general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection is performed. The devices can be used on vessels up to (and including) 7mm and tissue and/or vascular bundles as large as will fit in the jaws of the instruments.
The ENSEAL® G2 Articulating Tissue Sealers have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use these devices for these procedures.

**Technological Characteristics:**

The Ethicon Endo-Surgery ENSEAL G2 Articulating Tissue Sealers components are similar to the Predicate. The ENSEAL G2 Articulating Tissue Sealers have a 5 mm diameter shaft and are available in two shaft lengths: 35 and 45cm; and two jaw types: 3mm curved jaw and 5mm straight jaw. The jaws are normally in the opened position and can be partially or fully closed by squeezing the closing handle. The jaws have atraumatic teeth for grasping and holding targeted tissue when clamped. The handles of the Subject ENSEAL G2 Articulating Tissue Sealers have an ergonomic interface for the user. Like the Predicate, the Subject devices include an integrated energy activation button. The devices use a combination of the application of bipolar electrosurgical energy in conjunction with the I-BLADE knife, to compress, coagulate, and transect tissue.

In addition to the similar technological characteristics as the Predicate, the ENSEAL G2 Articulating Tissue Sealers instrument shaft device articulates approximately 60° to the left and the right of center. The instrument shaft can be articulated using the articulation wheel to gain additional access to tissue and facilitate the user's ability to target tissue and vascular bundles up to 60°. The top of the articulation wheel has a white arrow to indicate when the device shaft is straight and not articulated. When the articulation wheel is rotated clockwise, the shaft articulates to the right; when the articulation wheel is rotated counterclockwise, the shaft articulates to the left. While articulated, the device jaws seal and cut vessels, and cut, grasp and dissect soft tissue as intended. The Subject ENSEAL G2 Articulating Tissue Sealers performance is equivalent to the Predicate ENSEAL G2 Tissue Sealers.

**Performance Data:**

Ex-vivo and in-vivo tests were performed to verify that the performance of the ENSEAL G2 Articulating Tissue Sealers meets the definition of substantial equivalence to the Predicate device, ENSEAL G2 Tissue Sealers. Device performance was assessed against design requirements, including a 30-day chronic survival study, to demonstrate that the Ethicon Endo-Surgery ENSEAL G2 Articulating Tissue Sealers perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Incorporated
Mrs. Emily Kruetzkamp
Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

January 25, 2013

Re: K122797
Trade/Device Name: ENSEAL® G2 Articulating Tissue Sealers
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HGI
Dated: January 16, 2013
Received: January 22, 2013

Dear Mrs. Kruetzkamp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use Form**

**Indications for Use**

510(k) Number (if known): _____

Device Name: ENSEAL® G2 Articulating Tissue Sealers

Indications for Use:

The ENSEAL® G2 Articulating Tissue Sealers are indicated for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures.
The devices are bipolar electrosurgical instruments for use with the Generator GEN11 (GEN11). They are intended for use during open or laparoscopic, general and gynecological surgery to cut and seal vessels, and to cut, grasp and dissect tissue during surgery.
Indications for use include open and laparoscopic, general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection is performed. The devices can be used on vessels up to (and including) 7mm and tissue and/or vascular bundles as large as will fit in the jaws of the instruments.

The ENSEAL® G2 Articulating Tissue Sealers have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use these devices for these procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



Dwight Yen
2013.01.31 08:06:31 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number ___K122797___